REMARKS

Claims 1-35 remain in this application. Claims 1, 2, 5, 9, 10-14, 18, 23, 24, 26 and 31 are currently being amended. New claims 36-38 are currently being presented.

Support for New and Amended Claims

Support for new claim 36 and currently amended claims 1, 2, 9, 10-14, 18, 23, 24 and 31 can be found in the application, claims and drawing as filed. Support for specific claims can at least be found as listed below.

Claim	Support
1	Page 2, lines 3-19; page 6, lines 25-26.
2	Page 7, lines 11-18; page 4, lines 3-10; page 6, lines 25-26.
5	Page 4, lines 3-10.
9	Page 5, lines 23-29.
10	Page 6, lines 25-26.
11	Page 6, lines 25-26.
12	Page 6, lines 25-26.
13	Corrects grammatical error.
14	Page 6, lines 25-26.
18	Page 6, lines 25-26; page 2, lines 26-30.
23	Page 6, lines 25-26.
24	Page 5, lines 23-29.
26	Corrects typographical error.
31	Page 6, lines 25-26.
36	Page 5, lines 20-22; page 7, lines 11-13.
37	Page 5, lines 20-22; page 7, lines 11-13.
38	Page 5, lines 20-22; page 7, lines 11-13.

The amendment to the paragraph starting at page 7, line 11 and ending on page 7, line 18 corrects an obvious typographical error, the inadvertent omission of the word "generator."

Information Disclosure Statement

A Third Supplemental Information Disclosure Statement (IDS) is being filed concurrently herewith. Entry of the IDS is respectfully requested.

1. Rejections under 35 U.S.C. § 112

The Office Action states that Claims 1-2,5-6,9, 11, and 18 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Applicant respectfully submits that this rejection is moot in view of the amendments to the claims and the remarks below.

The meaning of the following terms is alleged to be unclear:

a. In claim 1, line l, "suitable".

This term has been deleted.

b. In claim 1, line l, "large".

Claim 1 has been amended to read, in relevant part "a previously habitable enclosed volume." Claim 1 as amended, and as originally filed, claims a method for fumigating an enclosed volume and restoring habitability, i.e., before the need for fumigation arose, the enclosed volume was habitable. "Habitable" is used in its conventional meaning: "suitable and fit for a person to live in: free from defects that endanger the health and safety of occupants." (Merriam-Webster's Dictionary of Law, 1996). As "habitable", the enclosed volumes to which the method can be applied are large enough to be occupied by at least one human being. The habitable enclosed volumes can be fixed or movable. Such habitable enclosed volumes include, but are not limited to, public, government (civilian and military), commercial and residential buildings and enclosed portions thereof. Also included are public, government (civilian and military), commercial and private vehicles, including aircraft, trailers, vessels and modular habitable containers. The amendment does not narrow the scope of this claim.

c. In claim 1, line 9, "under environmentally safe conditions".

This phrase has been deleted.

d. In claim 2, lines 2-3, "with the same equipment that was used".

Moot in view of amended claims 2, 5, 18 and new.

e. In claim 5, line 2,"emitter".

The term "emitter" is used in its conventional meaning of "that which emits." "Emit" also has its conventional meaning: "1. To send forth as a stream or emanation a. To send forth, discharge (as a liquid or plastic substance); to exude (juices, etc.). b. To give off, throw out ('effluvia', light, heat, ***gases***, flames, sparks, etc.)." Emphasis added, The Compact Edition of the Oxford English Dictionary, volume 1, page 853 (copy attached). An example of an emitter that is provided in the specification is a stripper (page 2, lines 26-30). See also page 5, lines 13-18 and Figure 1.

f. In claim 6, line 1, "the emitter is a stripper"

Stripping, or desorption, is the transfer of volatile components from a liquid mixture into a gas. Stripping involves the removal of one or more volatile components from a liquid by contacting it with a gas such as steam, nitrogen or air. Gas absorption, the inverse operation of stripping, is a unit operation in which soluble components of a gas mixture are dissolved in a liquid. (Fair, J.R., et al., Gas Absorption and Gas-Liquid System Design, pp. 14-1 to 14-98, at 14-4, 14-6 in Green, D., ed., Perry's Chemical Engineer's Handbook, 7th Ed., McGraw-Hill, New York, 1997). Scrubbers have been used to absorb a soluble gas from a mixture of gases, such as air. See generally, Fair, et al.; p. 14-91; scrubbing chlorine gas from air with aqueous caustic solution, Fair, et al., 14-8.

The preferred characteristics of suitable equipment to be used as an emitter are given at page 2, lines 26-30. Examples of suitable equipment are known in the art and commercially available. See Bulletin #055, "Solutions to Air Pollution Control. Corrosion Emissions Equipment," Plasticair, Inc. Optimization of such commercially available equipment, including minor modifications, are within the ability of the skilled practitioner, in view of standard teachings such as Fair et al.

In an embodiment of the present invention, chlorine dioxide dissolved in water is routed to an emitter that removes chlorine dioxide from the water and delivers chlorine dioxide in air to the volume to be fumigated (page 5, lines 12-15), i.e., by the process of stripping removes chlorine dioxide from solution in water and gives off ('emits") chlorine dioxide in air to the enclosed volume to be fumigated. See also page 5, lines 13-18 and Figure 1. In preferred

embodiments, the emitter is located within the volume requiring fumigation (page 4, lines 12-14).

g. In claim 9, line 2, "avoiding exceeding the dew point".

This phrase has been deleted. Amended claims 9 and 24 read "avoiding condensation" or "to avoid condensation." See the specification at least at page 5, lines 23-29.

h. In claim 11, lines 1-2, "requiring fumigation is a portion of a building".

This phrase has been deleted. The rejection is moot in view of amended claim 11.

2. Rejections under 35 U.S.C. § 103(a)

The Office Action states that claims 1-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenblatt et al (U.S.P.N. 4,681,739) in view of Smith et al (U.S.P.N. 4,780,333). The Applicant respectfully submits that this rejection is moot in view of the amendments to the claims and the remarks below.

a. The Office Action Does Not Characterize The Scope And Content Of the Prior Art

The Office Action correctly summarizes the factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966) that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) as: 1) determining the scope and contents of the prior art; 2) ascertaining the differences between the prior art and the claims at issue; 3) resolving the level of ordinary skill in the pertinent art; and 4) considering objective evidence present in the application indicating obviousness or nonobviousness. The Office Action, however, does not determine the scope and content of the prior art beyond characterizing the teachings of the two cited references. The Applicant respectfully submits that this determination of the scope and content of the prior art is at best incomplete, and that a more thorough determination of the scope and content of the prior art would demonstrate that the rejections under 35 U.S.C. § 103(a) are inappropriate and should be withdrawn.

1. The State of the Art of Anthrax Decontamination of Buildings Was Summarized In Testimony Before the U.S. House of Representatives Committee on Science on November 8, 2001.

The Science Committee held hearings in response to the contamination of the Hart Senate Office Building. The chairman of the committee, Rep. Sherwood Boehlert (R-NY) characterized the hearing as, "Decontamination 101 – a thoughtful, comprehensive overview of what we know and what we still need to know from acknowledged experts in the field." One of the witnesses, Mr. Manuel S. Barbeito, former Chief of the Aerobiology Control Division at the U.S. Army Biological Warfare Laboratories, discussed his successful decontamination of over 75 buildings at Fort Detrick, primarily using paraformaldehyde, stating "These decontaminations offered challenges and required ingenuity and tenacity to achieve success." When questioned by Committee members about current efforts to decontaminate the Hart Senate office building, Dr. Charles Haas of Drexel University stated, "We're engaged in a research project," calling the Hart building a "laboratory." Dr. James Baker, Jr. of the University of Michigan and NanoBio Corporation agreed, saying, "It is very important to remember that these decontamination protocols and processes are truly experiments. Nothing akin to this scale of building decontamination has been tried before, and it is not clear how effective this approach may be." See Press Release of November 8, 2001, "Anthrax Decontamination Is Ongoing 'Research Project'; Hart Building Is A 'Laboratory'," http://www.house.gov/science/press/107pr/107-120.htm also submitted April 5, 2002, as part of an Information Disclosure Statement as document AR, Baker, J., et al., Testimony Before Committee on Science of U.S. House of Representatives Hearing on "The Decontamination of Anthrax and Other Biological Agents", Nov. 8, 2001.

The testimony of Dr. Charles Haas was specifically directed to decontamination using chlorine dioxide. In summarizing the "State of Knowledge of Chlorine Dioxide Gas", Dr. Haas stated that the use of chlorine dioxide as a disinfectant/sanitizer applied directly as a gas is a development that has occurred over the past 20 years (http://www.house.gov/science/full/nov08/haas.htm, also submitted April 5, 2002, as part of an Information Disclosure Statement as document AR, Baker, J., et al., Testimony Before Committee on Science of U.S. House of Representatives Hearing on "The Decontamination of Anthrax and Other Biological Agents", Nov. 8, 2001). "Its use as a disinfectant for surfaces and implements (such as medical devices) was envisioned in a series of patents granted in the 1980's and 1990 (U.S. Pat. No. 4,908,188, issued March 13, 1990 to Jefferis et al., U.S. Pat.

No. 4,681,739 issued July 21, 1987 to Rosenblatt et al. [cited in the Office Action], U.S. Pat. No. 4,504,442 issued March 12, 1985 to Rosenblatt et al.)." However, Dr. Haas concluded this part of his testimony by stating: "There does not appear to be any information published in the refereed scientific literature concerning either the use of gaseous chlorine dioxide as a decontaminating agent for large buildings or spaces, or on the sensitivity of biological threat agents (including *Bacillus anthracis)* to either gas phase or liquid phase chlorine dioxide."

Dr. Haas concluded his testimony by raising several important research questions that remained unaddressed, including the following:

- What are the disinfectant concentration-time relationships yielding specific levels of inactivation and how are these affected by temperature, humidity and other environmental variables?
- What are the decomposition rates of chlorine dioxide and other disinfecting agents in a building environment, and what (if any) byproducts might be produced from these reactions? Are there undesirable effects on materials?
- What time lags exist to penetration of a gaseous disinfectant into all interior spaces that need to be disinfected? Can these be estimated by empirical rules or tests? Can sensors be developed to assess gaseous concentrations on a real time basis?
- What is the appropriate way in which to deploy verification samples prior to decontamination (both location and number), and what are the practical levels of inactivation that can be verifiably achieved?

The press release summarized the testimony, as noted above, and made the following points: While there was some experience with decontaminating buildings with paraformaldehyde, these decontaminations were characterized as offering challenges and requiring ingenuity and tenacity to achieve success. Although chlorine dioxide had been used for disinfection of tanks used in the processing of fruit juices, for microbial removal on produce and as a disinfectant for surfaces and implements (such as medical devices), citing U.S. Pat. No. 4,681,739 issued July 21, 1987 to Rosenblatt et al. for the last use, the extension of the available information to decontamination of a building was called "a research project," and the Hart Senate Office Building a "laboratory."

2. A Department of Energy Study That Included A Case Study Of The December 2001 Decontamination Of The Hart Senate Office Building Concluded That There Is A "General Lack Of Consensus" Regarding Decontamination Methods.

The question of the decontamination of people and buildings exposed to chemical and biological incidents was considered in detail in a report prepared by the Oak Ridge National Laboratory. See Vogt, B.M. & Sorensen, J.H., "How Clean is Safe? Improving the Effectiveness of Decontamination of Structures and People Following Chemical and Biological Incidents," Final Report prepared for the U.S. Department of Energy, Chemical and Biological National Security Program, ORNL/TM-2002/178, published October 2002, available at http://www.osti.gov/bridge. A copy is provided herewith in the accompanying Information Disclosure Statement.

The report was based on case studies including literature reviews and respondent interviews. A key research finding was that decontamination of buildings following the fall 2001 anthrax contamination in Florida, Washington DC and New York proved to be more difficult than envisioned in the early planning phases. It did provide a unique opportunity to investigate topics for which little empirical evidence existed. Vogt & Sorensen, page 11.

The report's summary of findings from the literature review indicates that although the techniques for performing decontamination are known and documented, experiences with the actual application to buildings indicate that implementing the techniques can be quite problematic.

> Solid surfaces in buildings can be decontaminated using biocides and hypochlorite solutions. Fumigation techniques are routinely used in closed building systems such as laboratories, but may prove to be difficult to use in complex building environments. Porous and textured surfaces, carpeting, and HVAC ducts are particularly problematic. Currently there are no defined standards for the decontamination of buildings exposed to biological agents. The wide disparities in the scientific literature make setting a reentry standard difficult. Vogt & Sorensen, page 25.

The case study of the Hart Senate Office Building decontamination reveals a number of findings that provide significant insights into the state of the art in Fall, 2001. On October 18, 2001, the EPA assumed primary authority for the decontamination of the Hart Senate Office Building and issued draft guidelines that specified formaldehyde for decontamination of rooms

and buildings. Concerns about the initially specified formaldehyde procedure forced EPA to seek other solutions, and chlorine dioxide gas was chosen as a less hazardous agent for the decontamination of the Hart building. Chlorine dioxide, which is used to purify water in many American and European communities, had not been used to kill anthrax in the field before this event, but it had been successful against bacteria that were considered even harder to destroy, according to Paul Schaudies, a microbiologist and a consultant to the EPA. By October 21st, the contracted technicians who were prepared to decontaminate Hart Building by pumping chlorine dioxide gas had to wait until scientists confirmed that the technique was an effective way to kill anthrax. Vogt & Sorensen, page 56. The fumigation of the Daschle suite of the Hart building began on December 1, 2001. Vogt & Sorensen, page 60. The building was reopened to Senators and staff on January 24, 2002. Vogt & Sorensen, page 60.

In summary, the report finds that there was a general lack of consensus of how to conduct decontamination of both buildings and people. The experience with the Hart Senate building illustrated the lack of standard protocols to clean up a structure following anthrax contamination. Vogt & Sorensen, page 74 It is especially worth noting that less that 6 weeks before the start of decontamination, there was still uncertainty as to whether chlorine dioxide should be used, and whether the technique of application would be an effective way to kill anthrax.

3. It Is Not Settled In The Art How Technologies Used In Laboratories To Inactivate Anthrax Spores Will Have to Be Modified For Use In Decontaminating Buildings Even In 2003.

A recent (June 2003) literature survey of publications from 1930 to 2002 by researchers at the U.S. Centers for Disease Control and Prevention is a useful measure of the scope and content of the prior art. See Whitney, E.A.S., et al., Inactivation of *Bacillus anthracis* Spores, Emerging Infectious Diseases 9 (6) June 2003 623-627, copy provided herewith in the accompanying Information Disclosure Statement. The authors stated that transfer of these sporicidal methods from the laboratory to a building has not yet been tested; however, the known laboratory results are a logical place to start when considering the decontamination of a building. The studies cited that use chlorine dioxide were performed in laboratory sterilizers, not in contaminated buildings. The use of formaldehyde and gamma radiation to decontaminate buildings is disclosed.

In general, the authors state that the decontamination of buildings from intentional release of *B. anthracis* is a new problem, and no accumulated scientific knowledge exists on the subject. Two areas of prior scientific research may be relevant: food processing and laboratory decontamination. With modification based on further study, the technologies used in laboratories and food processing plants may be applied to buildings. The authors conclude that although transferring the methods used to decontaminate or sterilize laboratory or food industry settings to decontaminating buildings may be useful, this transfer of methods has not been scientifically tested. "Further research is needed regarding improved methods for remediation of environments contaminated with *B. anthracis* spores, and the literature summarized here provides a basis for that effort."

Ronlan, U.S. Pat. No. 6,500,465, for Disinfecting and sporocidal composition and process for decontaminating buildings issued December 31, 2002 from application 10/086, 822, filed March 4, 2002. Ronlan discloses a volatile, residue free peroxide antimicrobial composition, which can be applied as a penetrating and durable, fine aerosol, that has superior strength with respect to decontaminating buildings infected with bacteria, fungi, virus or fungal or bacterial spores, as well as a process for decontaminating large man made structures and the air contained in these. Ronlan strongly teaches away from using chlorine dioxide for decontaminating buildings:

> Numerous attempts have been made to use oxidizing gases such as ozone or chlorine dioxide for decontaminating large buildings. However, the results have invariably been very disappointing. This is to some extent due to the inherent inability of gases to penetrate a porous structure within a reasonable time. In fine pores diffusion is the only way for a gas to spread, and this process is slow. Mainly, though, the failure of ozone and chlorine dioxide in building decontamination is due to the instability and extreme reactivity of these gases. They are very toxic to man and will also corrode virtually any oxidizeable material, (metals, wood, textiles, plants, plastics, etc.) Actually the major part of these gases will be consumed in unwanted oxidation reactions, that cause collateral damage, and for health and safety reasons is basically not possible to apply these gases at the levels required for efficient decontamination to take place. (column 1, lines 29-45).

There is certainly no unanimity that chlorine dioxide is the agent of choice for fumigating buildings contaminated with anthrax spores. Another agent, methyl bromide has been advocated as a preferable alternative by an University of Florida professor who has

deplored the EPA's recommendation of chlorine dioxide, a gas that he characterized as unstable and explosive, may not reach the desired target sites in buildings, and not previously registered for structural use. Woods, C. & Vendrame, C., UF Research on Anthrax Decontamination Confirmed by Illinois Tests, June 4, 2003 press release, http://www.napa.ufl.edu/2003news/anthrax.htm, visited 7/3/2003.

Given the scope and content of the prior art at the time the invention was made, Rosenblatt et al., U.S. Patent No. 4,681,739, discussed in detail below, would not have taught or suggested the present claimed invention.

b. Rosenblatt et al., U.S. Patent No. 4,681,739, Does Not Teach Or Suggest The Claimed Invention

Rosenblatt et al. discloses and claims methods of sterilizing articles, articles having gas impermeable surfaces and gas impermeable surfaces, in particular dental and medical implements and products (e.g., column 2, line 62 to column 3, line 12). "This invention provides a method for sterilizing microbiologically contaminated articles, such as the dry and gas impermeable surfaces of medical or dental implements or other articles contaminated with live bacteria and bacterial spores." Column 3, lines 22-26. Rosenblatt at column 4, lines 25-30 states: "Moreover, as described in greater detail below, when humidification is conducted in a closed exposure chamber, the chlorine dioxide gas may be introduced into the chamber while it still contains the humid air employed during the humidification procedure." When described in greater detail, the size of the exposure chamber disclosed in the working examples is 2 liters (column 7, lines 32-34; column 9, lines 58-61), and no guidance is provided to extend the disclosed method to habitable enclosed volumes. As recognized in the Office Action, Rosenblatt fails to restore habitability. The Rosenblatt reference thus does not teach or suggest the present claimed invention.

c. The Combination Of Smith et al. (U.S.P.N. 4,780,333) And Rosenblatt Does Not Teach Or Suggest The Claimed Invention.

The combination of the Smith reference with the Rosenblatt reference does not cure the defects of the Rosenblatt reference that are discussed above. The combined references neither

teach nor suggest the method for fumigating a previously habitable enclosed volume and contents and restoring habitability.

The Smith reference states that a method is provided of treating an air-contacted surface of an air conditioning system comprising the steps of: (A) introducing to the air passage and air-borne biocide in a biocidally effective amount; and (B) subsequently introducing into the air passage an air-borne biostat adapted to coat the surface with an air-driable, substantially water insoluble biostat coating, the biostat being introduced in an amount sufficient to coat the surface with a biostatically effective coating. According to another aspect, a kit is provided of interrelated parts for carrying out such treatment method.

Air conditioning systems are recognized as "items of equipment." See Aoyagi, U.S. Patent No. 6,363,734, column 1, lines 14-17. While it is necessary that part or all of a human body can be placed inside of air conditioning equipment for limited periods of time during construction, inspection and repair, air conditioning equipment, especially in an automobile, would not be considered habitable, i.e., suitable and fit for a person to live in.

The Office Action characterizes the Smith, reference as "the art of fumigating buildings using chlorine dioxide (col.1, lines 5-8 and col. 4, lines 22-24)." Smith at column 1, lines 5-8 states "The present invention is directed to a method of treating the air-contacted surfaces of an air conditioning system to deodorize such system and to reduce certain microbial growth therein." At column 4, lines 22-24 is found "The Alliger patent discloses a biocide composition produced by contacting a ClO_2 liberating material and a substantially water soluble acid component selected from the group consisting of organic acids and mixtures thereof with inorganic acid, the acid component comprising at least about 15% by weight lactic acid." Smith, column 4, lines 22-28). The Applicant's representative has been unable to find the terms "building", "habitable", "habitability" or "fumigate" in the Smith reference.

The Smith reference at column 6, lines 28-32 states "Care should be taken that there are no occupants in the motor vehicle or other space receiving the outflow of air from the air conditioning system to avoid unnecessary exposure to the biocide and biostat materials." This sentence merely states that there should be no occupants in the motor vehicle or adjacent space receiving the outflow of air from the air conditioning system ***during treatment*** of the air conditioning system with the biocide. It neither teaches nor suggests a method of restoring habitability of a habitable enclosed volume after treatment.

CONCLUSION

In view of the amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone call would expedite the prosecution of this case, the Examiner is invited to call the undersigned at (508) 416-2433.

Respectfully submitted,
BOWDITCH & DEWEY, LLP

By _____

Roger P. Zimmerman
Date: July 31, 2003
Registration No.: 38,670
Direct tel.: (508) 416-2433
Telephone: (508) 879-5700
Facsimile: (508) 929-3073

Bowditch & Dewey, LLP
161 Worcester Road
P.O. Box 9320
Framingham, Massachusetts 01701-9320